Complete Summary

GUIDELINE TITLE

Clinical practice parameters for hemodynamic support of pediatric and neonatal patients in septic shock.

BIBLIOGRAPHIC SOURCE(S)

Carcillo JA, Fields AI. Clinical practice parameters for hemodynamic support of pediatric and neonatal patients in septic shock. Crit Care Med 2002 Jun;30(6):1365-78. [162 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Septic shock

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Cardiology
Critical Care
Family Practice
Nursing
Pediatrics

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide clinical recommendations for hemodynamic support of neonates and children with septic shock

TARGET POPULATION

Pediatric and neonatal patients in septic shock

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

Recognizing signs and symptoms of septic shock

Treatment/Management

1. Fluid therapy
    - Crystalloid therapy (normal saline, lactated Ringers)
    - Colloid therapy (dextran, gelatin, 5% albumin)
2. Intravascular catheters and monitoring of central venous pressure and arterial pressure
3. Monitoring of heart rate, blood pressure, temperature, urine output, glucose and ionized calcium, oxygen saturation, and cardiac index
4. Packed red cell infusion
5. Vasopressor therapy
    - Dopamine
    - Norepinephrine
    - Epinephrine
    - Phenylephrine
    - Angiotensin/arginine vasopressin
    - Nitric oxide inhibitors (considered as investigational therapy only)
    - Methylene blue (considered as investigational therapy only)
6. Inotrope therapy
    - Dobutamine
    - Epinephrine/norepinephrine
    - Milrinone
    - Amrinone
7. Vasodilator therapy
    - Nitroprusside
    - Nitroglycerin
    - Milrinone
    - Amrinone
    - Prostacyclin
    - Phentolamine
    - Pentoxifylline

- Dopexamine

8. Glucose, calcium, thyroid, and hydrocortisone replacement
9. Therapy for persistent pulmonary hypertension of the newborn (PPHN)
    - Inhaled nitric oxide therapy
    - Metabolic alkalinization with sodium bicarbonate or tromethamine
    - Extracorporeal membrane oxygenation (ECMO)

MAJOR OUTCOMES CONSIDERED

- Resolution of shock
- Mortality rates
- Survival rates

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature was accrued by using MEDLINE and indexing the following age-limited keywords: sepsis, septicemia, septic shock, endotoxemia, persistent pulmonary hypertension, nitric oxide, and extracorporeal membrane oxygenation (ECMO).

NUMBER OF SOURCE DOCUMENTS

162

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Delphi Method)
Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Rating System for References

a. Randomized, prospective controlled trials
b. Nonrandomized, concurrent or historical cohort investigations
c. Peer-reviewed, state of the art articles, review articles, editorials, or substantial case series
d. Non-peer reviewed published opinions, such as textbook statements or official organizational publications

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The clinical parameters and guidelines were drafted by using a modification of the Delphi method. Briefly, the initial step included review of the literature and grading of the evidence by topic-based subcommittees during a 1-year period. Of interest, the committee found only four randomized controlled trials in children that examined the effect of hemodynamic support therapy on outcome from septic shock. Because of the paucity of outcome-directed, randomized controlled trials, the recommendations for hemodynamic support of term newborns and children in the original guideline document are primarily expert opinion rather than irrefutable evidence.

Grading of the literature and levels of recommendations were based on published American College of Critical Care Medicine criteria.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Rating Scheme for Recommendations

Level I: Convincingly justifiable on scientific evidence alone

Level II: Reasonably justifiable by scientific evidence and strongly supported by expert critical care opinion

Level III: Adequate scientific evidence is lacking but widely supported by available data and expert opinion

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Subcommittees were formed to evaluate each subtopic. The report from each subcommittee was compiled into a comprehensive document by the task-force chairperson. All members commented on the unified draft, and modifications were

made until < 10% of the task force disagreed with any specific or general recommendation. This process occurred during a 6-month period. Reviewers from the American College of Critical Care Medicine then requested further modifications that were performed.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of recommendations (I-III) are defined at the end of the "Major Recommendations" field.

Recommendations for Pediatric Septic Shock

Diagnosis

The inflammatory triad of fever, tachycardia, and vasodilation is common in children with benign infections. Septic shock is suspected when children with this triad have a change in mental status manifested as inconsolable irritability, lack of interaction with parents, or inability to be aroused. The clinical diagnosis of septic shock is made in children who have a suspected infection manifested by hypothermia or hyperthermia and have clinical signs of decreased perfusion, including decreased mental status, prolonged capillary refill of >2 seconds (cold shock) or flash capillary refill (warm shock), diminished (cold shock) or bounding (warm shock) peripheral pulses, mottled cool extremities (cold shock), or decreased urine output of <1 mL/kg/hr. Hypotension is not necessary for the clinical diagnosis of septic shock; however, its presence in a child with clinical suspicion of infection is confirmatory.

ABCs: First Hour of Resuscitation

Goals (Level III).

- Maintain airway, oxygenation, and ventilation
- Maintain circulation (defined as normal perfusion and blood pressure)
- Maintain threshold heart rates (Refer to Table 3 in the original guideline document for threshold heart rates and perfusion pressure for age)

Therapeutic End Points (Level III).

Therapeutic end points include capillary refill of <2 seconds, normal pulses with no differential between peripheral and central pulses, warm extremities, urine output >1 mL/kg/hr, normal mental status, and normal blood pressure for age.

Monitoring (Level III).

- Pulse oximeter
- Continuous electrocardiography
- Blood pressure
- Temperature

- Urine output
- Glucose and ionized calcium

Airway and Breathing (Level III). Airway and breathing should be rigorously monitored and maintained. Lung compliance and work of breathing may change precipitously. Patients typically manifest hypoxemia and metabolic acidosis and are at high risk to develop respiratory acidosis. The decision to intubate and ventilate is made on clinical diagnosis of increased work of breathing, hypoventilation, impaired mental status, or presence of a moribund state. Waiting for confirmatory laboratory tests is discouraged. Volume loading may be required during intubation because of relative or absolute hypovolemia. Induction agents that maintain cardiovascular integrity should be used.

Circulation (Level II). Vascular access should be rapidly attained. Establish intraosseous access if reliable venous access cannot be rapidly attained. Placement of central catheter access will usually be required for vasoactive infusions.

Fluid Resuscitation (Level II). Rapid fluid boluses of 20 mL/kg (isotonic saline or colloid) should be administered by push while observing for the development of rales, gallop rhythm, hepatomegaly, and increased work of breathing. In the absence of these clinical findings, fluid can be administered to as much as 200 mL/kg in the first hour. The average requirement is 40-60 mL/kg in the first hour. Fluid should be pushed with the goal of attaining normal perfusion and blood pressure.

Hemodynamic Support (Level II). Patients with severe shock uniformly require vasoactive support during fluid resuscitation. Vasoactive agents should be administered when a second catheter, preferably a central catheter, has been established. Dopamine can be used as the first-line agent; however, dopamine-resistant shock should be quickly recognized and epinephrine used for cold shock or norepinephrine used for warm shock to restore normal perfusion and blood pressure.

Hydrocortisone Therapy (Level III). Adrenal insufficiency should be suspected in catecholamine-resistant hypotensive shock in children with a history of central nervous system (CNS) abnormality or chronic steroid use or with purpura fulminans. Use of hydrocortisone in this situation may be lifesaving. Dose recommendations vary from a bolus of 1-2 mg/kg for stress coverage to 50 mg/kg for shock, followed by the same dose as a 24-hr infusion.

Stabilization: Beyond the First Hour

Goals (Level III).

- Normal perfusion
- Perfusion pressure (mean arterial pressure [MAP]-central venous pressure [CVP] or mean arterial pressure-intraabdominal pressure [MAP-IAP]) appropriate for age
- Superior vena cava or mixed venous oxygen saturation of >70%
- Cardiac index (CI) of >3.3 L/min/m^2 and <6.0 L/min/m^2

Therapeutic End Points (Level III).

Therapeutic end points are capillary refill of <2 seconds, normal pulses with no differential between peripheral and central pulses, warm extremities, urine output >1 mL/kg/hr, normal mental status, CI >3.3 and <6.0 with normal perfusion pressure (MAP-CVP or MAP-IAP) for age, and superior vena cava or mixed venous oxygen saturation >70%. Maximize preload to maximize CI.

Monitoring (Level III).

- Pulse oximetry
- Continuous electrocardiography
- Continuous intraarterial blood pressure
- Temperature
- Urine output
- Central venous pressure and oxygen saturation
- Pulmonary artery pressure and oxygen saturation
- Cardiac output
- Glucose and calcium

Fluid Resuscitation (Level II). Fluid losses and persistent hypovolemia secondary to diffuse capillary leak can continue for days. Ongoing fluid replacement should be directed at clinical end points, including perfusion, pulmonary capillary occlusion pressure, and cardiac output. Crystalloid is the fluid of choice in patients with hemoglobin >10 g/dL. Packed red blood cell transfusion can be given to children with hemoglobin <10 g/dL.

Hemodynamic Support (Level II). Hemodynamic support can be required for days in children with fluid-refractory shock. Children can present with low cardiac output and high systemic vascular resistance, high cardiac output and low systemic vascular resistance, or low cardiac output and low systemic vascular resistance shock. Although children with persistent shock frequently have worsening cardiac failure, hemodynamic states may completely change over time. A pulmonary artery catheter should be placed when poor perfusion, including reduced urine output, acidosis, or hypotension, persists despite use of hemodynamic therapies guided by clinical examination, blood pressure analysis, echocardiographic analysis, and arterial and superior vena cava oxygen saturation analysis. Children can respond to a change in hemodynamic therapeutic regimen with resolution of shock. Therapies should be adjusted to maintain mixed venous oxygen saturation >70%, CI of >3.3 L/min/m^2, and a normal perfusion pressure for age (MAP-CVP), with the ultimate goal of restoration of normal perfusion. There is no benefit to increasing oxygen delivery beyond the point of oxygen consumption plateau (critical point of oxygen delivery).

Shock with Low CI (Level II). Epinephrine is usually the first-line drug for dopamine-resistant shock. If hemodynamics are dependent on epinephrine and the cortisol level is <18 mg/dL, hydrocortisone at stress or shock doses may begin. If thyroxine (T4) or triiodothyronine (T3) level is low and sick euthyroid syndrome has been excluded, oral levothyroxine or, if necessary, intravenous liothyronine can be used to restore normal values for age.

Shock with Low CI, Normal Blood Pressure, and High Systemic Vascular Resistance (Level II). Nitroprusside or nitroglycerin are first-line vasodilators in patients with epinephrine-resistant shock and normal blood pressure. If cyanide or isothiocyanate toxicity develops from nitroprusside, or methemoglobin toxicity develops from nitroglycerin, or there is a continued low cardiac output state, then the clinician should substitute milrinone or amrinone. As noted above, the long half-life elimination of these drugs can lead to slowly reversible toxicities (hypotension or tachyarrhythmias), particularly if abnormal renal or liver function exists. Such toxicities can be reversed in part with norepinephrine infusion. Additional volume loading is necessary to prevent hypotension when loading doses are used.

Shock with High CI and Low Systemic Vascular Resistance (Level II). Norepinephrine is the drug of choice for age-dependent dopamine resistance. If hemodynamics are dependent on norepinephrine and the cortisol levels are <18 mg/dL, then hydrocortisone at stress or shock doses may be initiated. If the thyroxine or triiodothyronine level is low and sick euthyroid syndrome is excluded, then oral thyroxine or, if necessary, intravenous liothyronine can be given.

Refractory Shock (Level II). Children with catecholamine-refractory shock must be suspected to have unrecognized morbidities, including pericardial effusion, pneumothorax, hypoadrenalism, hypothyroidism, ongoing blood loss, intraabdominal catastrophe, necrotic tissue, and others. When these morbidities have been excluded, extracorporeal membrane oxygenation (ECMO) becomes an important alternative to consider. Currently, however, the expected survival is no greater than 50%. If the clinician suspects that outcome will be better with extracorporeal membrane oxygenation, flows >110 mL/kg may be required if vasodilation exists. Calcium concentration should be normalized in the red blood cell pump prime (usually requires 300 mg of calcium chloride [$CaCl_2$] per unit of packed red blood cells).

Recommendations for Newborn Septic Shock

Diagnosis

Septic shock should be suspected in any newborn with respiratory distress and reduced perfusion, particularly in the presence of a maternal history of chorioamnionitis or prolonged rupture of membranes. It is important to distinguish newborn septic shock from cardiogenic shock caused by closure of the patent ductus arteriosus in newborns with ductal dependent complex congenital heart disease. Any newborn with shock and hepatomegaly, cyanosis (a cardiac murmur), or differential upper and lower extremity blood pressures or pulses should be started on prostaglandin E_1 until complex congenital heart disease is ruled out by echocardiographic analyses. Newborn septic shock is typically accompanied by increased pulmonary artery pressures. Persistent pulmonary hypertension can cause right ventricle failure.

ABCs: First Hour of Resuscitation

Goals (Level III).

- Maintain airway, oxygenation, and ventilation

- Maintain circulation (defined as normal perfusion and blood pressure)
- Maintain neonatal circulation
- Maintain threshold heart rates

Therapeutic End Points (Level III).

Therapeutic end points include capillary refill of <2 seconds, normal pulses with no differential between peripheral and central pulses, warm extremities, urine output of >1 mL/kg/hr, normal mental status, normal blood pressure for age, difference in preductal and postductal oxygen saturation of <5%, and oxygen saturation of >95%.

Monitoring (Level III).

- Temperature
- Preductal and postductal pulse oximetry
- Intra-arterial (umbilical or peripheral) blood pressure
- Continuous electrocardiography
- Blood pressure
- Arterial pH
- Urine output
- Glucose and calcium

Airway and Breathing (Level III). Airway and breathing should be rigorously monitored and maintained. The decision to intubate and ventilate is made on clinical diagnosis of increased work of breathing or the moribund state. Volume loading is necessary during intubation and ventilation because of hypovolemia.

Circulation (Level III). Vascular access should be rapidly attained according to neonatal resuscitation program (NRP). Placement of an umbilical arterial and venous catheter is preferred. If these catheters cannot be placed, a peripheral arterial and peripherally positioned central catheter can be placed.

Fluid Resuscitation (Level II). Rapid fluid boluses of 10 mL/kg should be administered, observing for the development of rales, hepatomegaly, and increased work of breathing. Up to 60 mL/kg may be required in the first hour. Fluid should be pushed, with a goal of attaining normal perfusion and blood pressure.

Hemodynamic Support (Level II). Patients with severe shock uniformly require vasoactive support during fluid resuscitation. Although dopamine can be used as the first-line agent, its effect on pulmonary vascular resistance should be taken into account. Usually, a combination of dopamine at low dosage (<8 mg/kg/min) and dobutamine (up to 30 micrograms/kg/min) is used; if the patient is not responsive to therapy, then epinephrine should be infused to restore normal blood pressure and perfusion.

Persistent Pulmonary Hypertension of the Newborn (PPHN) Therapy (Level II). Hyperoxygenate initially with 100% oxygen, and institute metabolic alkalinization (up to pH 7.50) with sodium bicarbonate ($NaHCO_3$) or tromethamine. Mild hyperventilation can also be instituted until 100% oxygen saturation and <5%

difference in preductal and postductal saturations are obtained. Therapeutic narcosis with fentanyl and paralysis with neuromuscular blockers should be considered to reduce pulmonary blood pressures in ventilated patients without response to the PPHN therapy outlined above. Inhaled nitric oxide should be administered when available.

Stabilization: Beyond the First Hour

Goals (Level III).

- Maintain threshold heart rate
- Maintain normal perfusion and blood pressure
- Maintain neonatal circulation
- Central venous oxygen saturation >70%

Therapeutic End Points (Level III).

- Capillary refill <2 seconds, normal pulses with no differential between peripheral and central pulses, warm extremities, urine output >1 mL/kg/hr, normal mental status, normal blood pressure for age
- >95% peripheral oxygen saturation
- <5% difference in preductal and postductal saturation
- Central venous oxygen saturation >70%
- Absence of right-to-left shunting, tricuspid regurgitation, or right ventricular failure on echocardiographic analysis

Monitoring (Level III).

- Pulse oximetry
- Arterial pH
- Continuous electrocardiography
- Continuous intra-arterial blood pressure
- Temperature
- Glucose and calcium
- Urine output
- Central venous pressure and oxygen saturation

Fluid Resuscitation (Level II). Fluid losses and persistent hypovolemia secondary to diffuse capillary leak can continue for days. Ongoing fluid replacement should be directed at clinical end points, including perfusion and CVP. Crystalloid is the fluid of choice in patients with hemoglobin >12 g/dL. Packed red blood cell transfusion can be added in newborns with hemoglobin <12 g/dL.

Hemodynamic Support (Level II). The pulmonary vascular reactivity will tend to decrease after 5 days of life, although this should be evaluated carefully before stopping therapies directed at PPHN. In the patient with suprasystemic pulmonary hypertension, right ventricle failure may accompany shock. This can make inotrope and vasopressor therapies less effective at supporting cardiac output. Therapies directed at reducing pulmonary artery pressure are paramount. Inhaled nitric oxide can be given with greatest effects usually found at 20 ppm. In newborns with poor left ventricle function and normal blood pressure, the addition

of nitrosovasodilators or type III phosphodiesterase inhibitors can be effective but must be monitored for toxicities. It is important to volume load when using these systemic vasodilators.

ECMO Therapy for Refractory Shock (Level II). Newborns with refractory shock must be suspected to have unrecognized morbidities, including pericardial effusion, pneumothorax, ongoing blood loss, hypoadrenalism, hypothyroidism, inborn errors of metabolism, or cyanotic or obstructive heart disease. When these causes have been excluded, ECMO becomes an important therapy to consider. The expected ECMO survival rate for newborn septic shock is currently 80%. Most centers accept refractory shock or a PaO_2 <40 mm Hg after maximal therapy to be sufficient indication for ECMO support. ECMO flows of >110 mL/kg may be required when vasodilation exists. When administering venoarterial ECMO, persistent hypotension or shock should be treated with dopamine or epinephrine because vasodilation is the likely cause. The venoarterial system provides inotropic support. Inotrope requirements frequently lessen when venoarterial ECMO is used. Calcium concentration should be normalized in the red blood cell pump prime (usually requires 300 mg of $CaCl_2$ per unit of packed red blood cells).

Definitions

Rating System for Recommendations

Level I: Convincingly justifiable on scientific evidence alone

Level II: Reasonably justifiable by scientific evidence and strongly supported by expert critical care opinion

Level III: Adequate scientific evidence is lacking but widely supported by available data and expert opinion

CLINICAL ALGORITHM(S)

Algorithms are provided for the management of hemodynamic support in infants and children and for the management of hemodynamic support in term newborns.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

- The type of supporting evidence is identified for select recommendations (see the "Major Recommendations" field).
- Because of the paucity of outcome-directed, randomized controlled trials (only four randomized controlled trials were found), the recommendations for hemodynamic support of term newborns and children in the original guideline document are primarily expert opinion rather then irrefutable evidence.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Improved outcomes in neonatal and pediatric sepsis

POTENTIAL HARMS

- Rapid administration of fluid may cause left-to-right shunting through the ductus, with ensuing congestive heart failure induced by ventricular overload.
- Increases above 12-15 mm Hg pulmonary capillary occlusion may be associated with decreased survival.
- Fresh-frozen plasma should not be pushed because it has hypotensive effects.
- Amrinone and milrinone may cause tachyarrhythmias, hypotension, or diminished systemic vascular resistance.
- Nitrosovasodilators may cause hypotension or nitrosovasodilator-associated toxicity (cyanide or isothiocyanate toxicity from nitroprusside or methemoglobin toxicity from nitroglycerin).
- Extracorporeal membrane oxygenation (ECMO) therapy is associated with complications (e.g., bleeding and infection) in neonates with septic shock.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Carcillo JA, Fields AI. Clinical practice parameters for hemodynamic support of pediatric and neonatal patients in septic shock. Crit Care Med 2002 Jun;30(6):1365-78. [162 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2002 Jun

GUIDELINE DEVELOPER(S)

American College of Critical Care Medicine - Professional Association

SOURCE(S) OF FUNDING

Society of Critical Care Medicine (SCCM)

GUIDELINE COMMITTEE

American College of Critical Care Medicine Task Force

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Society of Critical Care Medicine (SCCM) Web site.

Print copies: Available from the Society of Critical Care Medicine, 701 Lee Street, Suite 200, Des Plaines, IL 60016; Phone: (847) 827-6869; Fax: (847) 827-6886; on-line through the SCCM Bookstore.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Dorman T, Angood PB, Angus DC, Clemmer TP, Cohen NH, Durbin CG Jr, Falk JL, Helfaer MA, Haupt MT, Horst HM, Ivy ME, Ognibene FP, Sladen RN, Grenvik AN, Napolitano LM. Guidelines for critical care medicine training and continuing medical education. Crit Care Med 2004 Jan;32(1):263-72.

Electronic copies: Available in Portable Document Format (PDF) from the Society of Critical Care Medicine (SCCM) Web site.

Print copies: Available from the Society of Critical Care Medicine, 701 Lee Street, Suite 200, Des Plaines, IL 60016; Phone: (847) 827-6869; Fax: (847) 827-6886; on-line through the SCCM Bookstore.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on February 13, 2003. The information was verified by the guideline developer on April 10, 2003.

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